K063313

8 510(k) Summary

NOV 17 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

I. General Information

Date of summary preparation: September 18, 2006

Manufacturer
Siemens AG, Medical Solutions
Henkestrasse 127
D-91052 Erlangen, Germany

Headquarters:
Siemens AG
Wittelsbacherplatz 2
D-80333 Munich, Germany

Registration Number 8010024

Importer/Distributor
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Registration Number 2240869

Contact Person
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Regulatory Affairs Manager
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Classification and Device Name

Classification Panel:	Radiology
Classification Name:	Magnetic Resonance Diagnostic Device Accessory
Device Class:	Class II [21 CFR § 892.1000]
Product Code:	LNH
Common Name:	Special Purpose Coil
Trade Name:	Flex Loop Coil Set 3 T

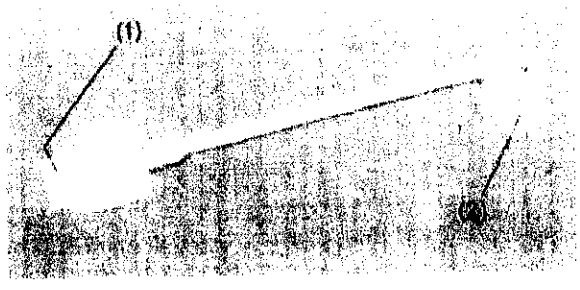
II. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use

The intended use of the Flex Loop Coil Set 3 T is, in conjunction with a Magnetic Resonance Scanner, the MR examination of the human body. Used in the MAGNETOM 3 T Trio, A Tim System, the Flex Loop Coils are intended to produce transversal, sagittal, coronal and oblique images of the internal structures of the body.

Device Description

The Flex Loop Coil Set 3 T consists of five receive-only coils and one interface, which contains the preamplifiers, cable traps and a combiner network. The coils are two 4-channel flexible coils (Flex Coil Large and Flex Coil Small) and three linear polarized (LP) flexible coils (Loop Coil 4 cm, 7 cm and 11 cm).

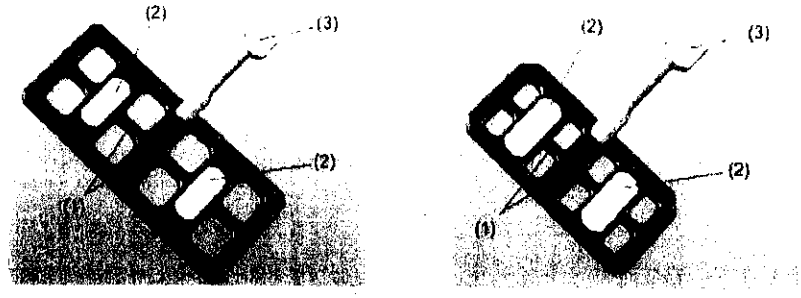


(1) Coil socket
(2) Plug for coil socket on the patient table

Figure 10: Flex loop interface

(1) Coil loop
(2) Coil plug

Figure 11: Loop coils 4 cm, 7 cm, 11 cm



(1) Center markings
(2) Electronic boxes
(3) Coil plug

(1) Center markings
(2) Electronics boxes
(3) Coil plug

Figure 12: Flex Coil large and small

Equivalency Information

Siemens believes that the Flex Loop Coil Set 3 T for MAGNETOM Trio, a Tim System is substantially equivalent to the Flex Loop Coil Set for MAGNETOM 1.5 T systems described in the following submissions.

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens MAGNETOM 1.5 T Symphony	K971684	Aug. 05 1997
Siemens MAGNETOM 1.5 T Avanto	K032428	Oct. 16 2003
Siemens MAGNETOM 3 T Trio, a Tim System	K050200	Feb. 28 2005

Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device
Although the new Flex Loop Coils are designed for a field strength of 3 T, we believe that they are substantially equivalent to the predicate Flex Loop Coils for 1.5 T MAGNETOM Systems.

General Safety and Effectiveness Concerns
The following safety and performance parameters:

[Safety]
- Maximum Static Field
- Rate of Change of Magnetic Field
- RF Power Deposition
- Acoustic Noise Level

[Performance]
- Geometric Distortion
- Slice Profile, Thickness and Gap
- High Contrast Spatial Resolution

specified by the FDA Guidance document for MR Diagnostic Devices are unaffected by the modifications described within this notification.

The following parameters were considered for the new Flex Loop Coil Set 3 T

[Safety]
- Biocompatibility

[Performance]
- Signal to Noise Ratio
- Image Uniformity

No new materials were used for the new Flex Loop Coil Set 3 T compared to their predicate devices. Therefore no biocompatibility tests were performed. Signal to Noise Ratio (SNR) and image uniformity tests acc. to NEMA MS-6 standard were performed for the new Flex Loop Coil Set 3 T and the results presented in this submission show that they are equivalent with the predicate devices.

Conclusion as to Substantial Equivalence
Laboratory and clinical testing was performed to support this claim of substantial equivalence and to show that the technological differences do not raise any new questions pertaining to safety and effectiveness.

Date: 18.October 2006

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: Premarket Notification

To Whom It May Concern:

Enclosed in duplicate is the following information:

A. Purpose of Submission: Special 510(k)

B. Name and Address of the Third Party:

TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

C. Name and Address of the Manufacturer:

Siemens Medical Solutions
Henkestrasse 127
91052 Erlangen, Germany

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Siemens Medical Solutions
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV Product Service
1775 Old Hwy 8 NW, Ste 104
NEW BRIGHTON MN 55112-1891

NOV 17 2006

Re: K063373
Trade/Device Name: Flex Loop Coil Set 3 T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: October 20, 2006
Received: November 8, 2006

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2 Indications for Use Statement

510(k) Number (if known) K063373

Device Name: Flex Loop Coil Set 3 T

Indications for Use:

The intended use of the Flex Loop Coil Set 3 T is, in conjunction with a Magnetic Resonance Scanner, the MR examination of the human body.

Used in the MAGNETOM 3 T Trio, a Tim System, the Flex Loop Coils are indicated for use as a diagnostic imaging device to produce transversal, sagittal, coronal and oblique images of the internal structures of the body. The images produced by the MAGNETOM 3 T Trio, a Tim System with the Flex Loop Coils reflect the spatial distribution of protons (hydogen nuclei) exhibiting magnetic resonance.

When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

The intended use of the MAGNETOM 3 T Trio, a Tim System is not affected in any way by the use of the new Flex Loop Coil Set 3 T.

Prescription Use X
(Part 21 CFR 801 Subpart D)

~~AND~~/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063373